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SECTION 2: SUMMARY AND CERTIFICATION
510(K) SUMMARY

Safety and effectiveness information concerning the Bio-logic Evoked Potential product and this device modification is summarized below.

Because this is not a CLASS III device, the special certification defined for this section is not required.

PREPARED BY: Bio-logic Systems Corp
One Bio-logic Plaza
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TELEPHONE: (847)-949-5200

CONTACT PERSON: Norman E. Brunner

DATE ON WHICH THE SUMMARY WAS PREPARED: March 26, 2003

NAME OF DEVICE: Bio-logic Evoked Potential System.

COMMON NAME: Evoked Response System.

CLASSIFICATION NAME: Evoked Response Auditory Stimulator (per CFR 882-1900).

PREDICATE DEVICE: Bio-logic Navigator Pro, reference 510(k) #K994149.

DESCRIPTION OF THE DEVICE:

The Bio-logic Auditory Evoked Potential (AEP) family of products is used for the recording, display, computation, and manipulation of human physiological data, for auditory screening purposes and to provide assistance in the neurological assessment and treatment of auditory sensory disorders. The predicate device referenced above is the latest in a series of complete systems of this type marketed by Bio-logic.

The Navigator Pro Evoked Potential Predicate Device performs Auditory Brainstem Response (ABR) recording functions with two channels of simultaneous data recording. The software for the Navigator Pro implements the standard ABR functions common to most similar systems on the market for many years.

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The standard ABR test works on the basis of repeating a stimulus-response cycle. An auditory stimulation (click, tone, etc.) is presented to the patient through the use of an earphone or headphones. The EEG response from the brain is read through the use of one or more scalp electrodes placed on the patient. The response time of interest is approximately from 1 – 20 milliseconds following the stimulus. The response voltage readings for this time period are amplified, digitized and stored in the AEP system computer's memory. The stimulation is then repeated, the EEG response is read again, and this cycle is repeated many times . Each time the response is read, it is averaged together with all previous responses. The final data record is the result of averaging several thousand (usually 2000-3000) responses. This averaging process is necessary because the ABR signal is very small, much lower in voltage than the surrounding EEG "noise" present in the recording. The noise is averaged out over the many readings, because the noise will have a very low average net value. The result from the averaging process will be the signal.

The reason for this 510(k) is that the software for the host computer (PC) in the Evoked Potential system has been modified. The host computer software for the Predicate Device is DOS-based, whereas the host software for this modified Bio-logic AEP program is WINDOWS-based. The WINDOWS program has the same features and functionality as that of the predicate device, but with improved user interfaces and overall ease-of-use. The functions of the hardware are the same as those of the Predicate Device (Navigator Pro) hardware. The host computer software for control of the hardware has the same functionality as that of the DOS-based Predicate Device software. Direct hardware control of all Navigator Pro functions is provided from the Digital Signal Processor (DSP) and its program code located inside the Navigator Pro module, instead of directly from the host computer program. (There are no changes to the DSP program code in the Navigator Pro module as a result of this host computer software modification.) By distributing the hardware-specific functions to the DSP, the Windows-based host computer program has fewer real-time demands, and performance and reliability are improved. Together, the hardware and software implement the same functionality and perform the same intended use as the Predicate Device, but with improved ease-of-use and flexibility for the user.

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INTENDED USE:

The Bio-logic Evoked Potential (EP) product family is indicated for use in the recording and display of human physiological data, for auditory screening purposes and to assist in determining possible auditory and hearing-related disorders. Auditory stimuli are presented to the patient's ear through an earphone or headphones, and the corresponding Auditory Brainstem Responses (ABR) from the patient are recorded using EEG electrodes placed on the scalp. Standard ABR testing is most used clinically for 2 reasons: (1) to predict behavioral audiometric thresholds, and (2) as an audiological testing tool to assist in the assessment of possible auditory nervous system abnormalities.

The Bio-logic Navigator Pro EP System can be used for patients of all ages, from children to adults, including infants and geriatric patients. The use of the Bio-logic EP family of products is to be performed under the prescription and supervision of a physician or other trained health care professional.

SAFETY AND EFFECTIVENESS SUMMARY

To establish the safety and effectiveness of this modification to the Bio-logic Evoked Potential software, the modification was designed and incorporated into the product in accordance with the Bio-logic internal Product Development procedures, which are intended to meet ISO-9001, ISO-13485 and FDA QSR Design Control specifications. A detailed Hazard/Risk analysis for the EP family of products was performed using the Fault Tree analysis (FTA) approach, and a detailed Risk Assessment for the modified Evoked Potential product was written in accordance with ISO-14971, the International Standard: Application of Risk Management to Medical Devices.

As with the Predicate Device, the modified software does not make any final decisions that result in any automatic forms of diagnosis or treatment. All program "recommendations" are subject to review by a qualified health care professional, and may be modified, overridden or deleted as determined by the qualified user. The program provides functions to allow the qualified user to review all raw data collected and perform other data analysis to suit his or her requirements.

The chart on the following page provides a summary comparison of the technological characteristics of the modified Evoked Potential device relative to the predicate Navigator Pro device. This is to demonstrate that this Modification to Bio-logic Evoked Potential for Navigator Pro has no significant differences which would adversely affect product safety and effectiveness.

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Parameter for comparison	Similarity or Difference
Intended Use	No differences.
Population	No differences.
Hardware Configuration	No differences. Both devices use the Navigator Pro patient connection hardware module.
Computer Control Software	The modified Evoked Potential device has changes to the AEP software program running in the PC (host computer). These changes allow full use of the Windows operating system functions and GUI features. The Predicate Device uses the DOS operating system or runs in a "DOS Window" with very little Windows compatibility.
Patient information and tracking.	No differences.
Patient connections (transducers and electrodes)	No differences.
Host Computer to Patient Connection Module Communications	No differences. The communication from the PC (host computer) to the Navigator Pro patient connection module is provided through a serial port cable for both devices.
Presentation of Data / User Interface	Changes have been made in the modified device software to incorporate GUI features and functionality common to most Windows programs on the market today. Computer system users are very familiar with standard Windows features. Therefore, these changes increase ease-of-use and provide improved flexibility and efficiency for the user, with no significant changes to the underlying AEP features and functions.
Physical Characteristics	No differences.
Safety Characteristics	No differences. The patient connection and isolation circuits are the same for both products.
Product Labeling	No differences.
Anatomical sites.	No differences.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2003

Mr. Norman E. Brunner
Vice-President of Research and Development
Bio-logic Systems Corporation
One Bio-logic Plaza
Mundelein, Illinois 60060-3700

Re: K031009
Trade/Device Name: Modification to Bio-logic Evoked Potential (EP) System
Regulation Number: 21 CFR 882.1900
Regulation Name: Evoked response auditory stimulator
Regulatory Class: II
Product Code: GWJ
Dated: March 28, 2003
Received: March 31, 2003

Dear Mr. Brunner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031009

Device Name: Bio-logic Evoked Potential System.

Indications For Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031009

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)